June 30, 2020

National Government Services Medical Policy Unit
P.O. Box 7073
Indianapolis, IN 46207-7073
PartBLCDComments@anthem.com
ATTN: Craig Haug, M.D., Medical Director

Re: Proposed LCD for Percutaneous AQV Fistula for Hemodialysis (DL38573)

Dear Dr. Haug:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. Part of RPA’s mission is to promote excellence in the delivery of high-quality kidney care within an environment that supports patient access to care and safety.

RPA commends NGS for the prompt issuance of the Local Coverage Determination (LCD) on Percutaneous AV Fistulas (pAVF) for Hemodialysis, DL38673. However, we strongly recommend that NGS cover both the Ellypsis and WavelinQ systems for percutaneous fistula creation.

Our members care for patients with chronic kidney disease and end-stage kidney disease across the country. Ensuring that these patients have access to successful creation of a hemodialysis fistula is of paramount importance to their treatment. While the surgery is relatively straightforward and able to be performed in both the hospital and non-hospital settings, it does require significant experience and skill. Even in skilled hands, open surgical fistula outcomes have not been optimal, with approximately 60% failing to mature adequately to be used for dialysis and thereby requiring multiple subsequent procedures to augment maturation. Vascular complications such as distal ischemia or steal syndrome are also relatively common. These barriers cause many patients to begin hemodialysis with a catheter resulting in prolonged catheter use.
pAVF expands patient access to hemodialysis fistula creation by expanding their options both by increasing the available pool of physicians to all those who have endovascular procedure skills (surgeons, interventional radiologists, and interventional nephrologists) as well as increasing the possible techniques and anatomical locations for fistula creation. The Ellypsis procedure requires predominantly ultrasound skills while the WavelinQ procedure principally uses angiographic skills. While many physicians are skilled in both of these areas, a number have more focused capability involving either ultrasound or angiography.

Additionally, these two techniques complement one another by increasing the number of potential locations for pAVF creation. Open surgical creation of a fistula is typically done in the wrist (radiocephalic fistula --36821) or elbow (brachiocephalic fistula 36821). Less frequently, an open proximal radial artery fistula (36821) or transposed fistula (36818, 36819, 36820) can be done using the same vessels. Alternatively, the Ellypsis procedure allows for a less invasive approach for making a proximal radial artery fistula, while the WavelinQ procedure supports both a proximal radial artery fistula or an ulnar artery fistula construction. Coverage for both percutaneous fistula procedures will provide a wide range of fistula alternatives to meet patient needs. While it is too early to know how many people will benefit from a percutaneous fistula due to selection bias inherent in the device pivotal studies, the real world experience today suggests that 20-40% could be candidates for pAVF if both procedures are covered services; if only one procedure is covered, it is likely there will be fewer options and thus fewer pAVF developed. RPA does recognize that this is a lower penetration than either company theorizes, but still agrees that having both procedures as covered services will allow for greatest access opportunities for patients for fistula creation.

Without summarizing the literature related to the efficacy of the Ellypsis and WavelinQ procedures, both procedures have proven to be at least as effective as the current standard of care, open surgical fistula creation. Both procedures received FDA approval, CMS new technology APC codes, and more recently the individual G codes (G-2170 and G-2171). Both procedures have six-and twelve-month follow-up data which should be sufficient for a new technology to receive coverage. Delaying payment until 2 or more years to gather follow-up data would significantly impair innovations that improve patient outcomes. It is worth noting that the AMA CPT Editorial Panel would not require longer than twelve-month follow-up to grant a Category 1 CPT code to a new procedure.

Finally, both of these procedures have demonstrated appropriate safety profiles to receive FDA approval as currently marketed. Peer reviewed literature does demonstrate a low level of arterial complications with open surgery or either percutaneous fistula procedure. Initially, the WavelinQ procedure using a 6 French device had a higher rate of arterial complications, but that rate has improved with the introduction of a 4 French device. Published complication rates do not differ significantly between two pAVF approaches, though the Ellypsis rate is slightly lower.
As noted, there are certainly more reports related to the WavelinQ procedure within the MAUDE database. RPA believes it is important to recognize that the FDA uses this database to provide ongoing monitoring of approved devices, particularly new technologies after they have been released. However, they specifically warn against using that database to assess the rate of adverse events (due to lack of denominator information) or compare different devices (due to reliance on self-reporting). The FDA language on this point reads as follows:

**MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices.**

Recognizing the FDA’s caution about the proper use of this database, RPA believes coverage decisions should be based upon safety as reported in the appropriate peer reviewed medical literature. We therefore do not support broadly using the MAUDE database to compare the safety profiles of different technologies. RPA has performed a detailed review of safety events in the MAUDE database and we believe it is apparent that the number of safety events reported are very similar to the level reported in the peer reviewed literature upon which FDA approval was granted.

As always, RPA welcomes the opportunity to work collaboratively with NGS in its efforts to improve the quality of care provided to its jurisdictions’ kidney patients, and we stand ready as a resource to NGS in its future work on local coverage issues. Any questions or comments regarding this correspondence should be directed to RPA’s Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

Jeffrey A. Perlmutter, MD
President